DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

Tyrell, Inc.
c/o Ms. Darla J. Elkin
Director, Regulatory Affairs, Quality Systems
Synergos, Incorporated
2202 Timberloch Place, Suite 230
The Woodlands, Texas 77380

Re: K043377
Trade/Device Name: Zeno
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 2,2005
Received: March 3,2005

Dear Ms. Elkin:

This letter corrects our substantially equivalent letter of June 1,2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

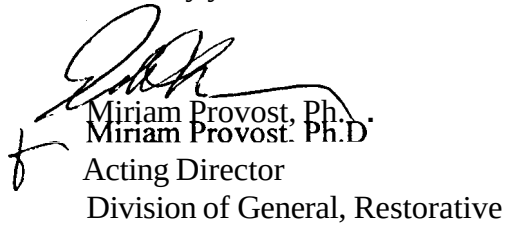
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Miriam Provost, Ph.D.
Miriam Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
Tyrell, Incorporated – Zeno™ Acne Device

Indications for Use

510(k) Number: K043377

Device Name: Zeno

Indications For Use: Zeno is indicated *for* the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

[illegible] Division of General, Restorative and Neurological Devices

K043377

JUN 1 - 2005

K043377

510(k) SUMMARY
TYRELL, INCORPORATED – Zeno Acne Device

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Sponsor's Name and Address: Tyrell, Inc.
515 West Greens Road, Suite 725
Houston, TX 77067

Telephone: (281) 880 – 6541
Facsimile No. (281) 880 - 6702

Submittor Information: Darla J. Elkin
Director, Regulatory Affairs, Quality Systems
SYNERGOS, Inc.
2202 Timberloch Place, Suite 230
The Woodlands, TX 77380-1109

Telephone No.: (281) 367-6655
Facsimile No.: (281) 367-9679

Device Trade Name: Zeno™

Common Name: Acne Treatment Device

Classification: Class II

Predicate Devices: National Biological Corporation
Derma-Wand
K982082

CureLight Ltd.
ClearLight Phototherapy System, Model CI 420
K013623

Radiancy (Israel) Ltd.
Radiancy Acne System With ClearTouch Light Unit A
K032205

Description of the Device

Zeno is a portable hand-held device that produces accurately controlled low level sustained heat for use in treating dermatological disorders, specifically, mild to moderate acne. Individual acne blemishes are treated for a preset time of 2 ½ minutes at a preset temperature. The treatment tip is made from a biocompatible material and delivers the specific low-level heat to the individual acne blemish. The device is powered by rechargeable AAA nickel-metal hydride batteries.

Indications for Use

Zeno is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Performance Data

Preclinical and clinical testing performance testing was conducted with Zeno.

- **Preclinical Testing**

  In vitro testing demonstrated significant sensitivity of *p. acnes* bacterial cells to the effects of sustained low-level heat.

  Biocompatibility testing of the tip material was conducted in accordance with the ISO 10993 Biological Testing of Medical and Dental Materials and Devices and the tip material is considered biocompatible.

  Zeno was tested for EMI in accordance with the IEC 60601-1 standard. Zeno operates within the EMI emission, susceptibility and static discharge levels specified in the IEC 60601-1 standard.

  Clinical Testing

  Clinical testing was conducted in both a controlled practitioner office environment and a consumer home-use environment and submitted as part of the 510(k) application to confirm that Zeno is as safe and effective as the predicate device. The controlled clinical study design was a randomized, doubled-blinded study.

Substantial Equivalence

The Zeno and its predicate devices are all devices that use either light or heat to treat the dermatological condition of mild to moderate acne by exposing the surface of the skin to the light at precise wavelengths and temperatures or heat at precise temperatures. Although there are differences in the technological characteristics of the Zeno and its predicate devices, those differences do not raise new questions of safety or efficacy. Another difference is Zeno will be available over the counter (OTC) versus the predicate device which is prescription use only however there are no new safety or efficacy concerns regarding this use as evidenced by the clinical testing that was conducted on Zeno. Thus, Zeno is substantially equivalent to the predicate device for treatment of mild to moderate acne.

Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed device has been shown to be safe and effective for its intended use.